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SACRAMENTO, CALIFORNIA 95817

Public Comment:

I would like to comment on the following:

Docket No. 00D-1497,  
Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Service  
Food and Drug Administration.  
5630 Fishers Lane, Room 1061, (HFA-305  
Rockville, MD 20852

Date: September 25, 2000

I have a question concerning the AEC performance in the contact configuration 900.12(e)(10).

After October 28, 2002 the new compliance is +/- .15 for the density range of cassettes.

The current range is +/- .30.

This is not consistent with CFR 900.12(e)(12) Weekly quality control test. (ii) The optical density of the film at the center of the phantom image shall not change by more than <plus-minus> .20 from the established operating level.

I have 3 mammo units and I have 28 18x24 cassettes and 25 24x30 cassettes. Under the current standard of .30 all cassettes are in compliance. Under the new 2002 compliance over 1/2 of the cassettes 14 18x24 and 9 24x30 would have to be replaced at great expense to the department.

There is no guarantee that the new replacement cassettes will fall under the standard. One reason for the variation is that the cassettes might have different emulsions in them. We currently open 2 boxes of film per day (200 sheets) On the Third day we are changing cases of film and emulsions.

Here is the dilemma. Under your own guidance when the phantom has an accepted compliance of .2 so should the density range on the cassettes and screens. The phantom is performed on a single cassette (same cassette) each week and it is from the mid range of the entire cassettes in the department. This easy to control. When the entire range of cassettes is tested you can not control the density so precisely. It should remain at +/- .30 density difference.

I propose that this be looked at this new compliance and reconsider it.

Thank you,

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